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**Testimony of the
American Thoracic Society
before the Energy and Power Subcommittee
of the House Energy and Commerce Committee
Presented by Monica Kraft, MD
President of the American Thoracic Society
Wednesday, July 18, 2012.**

I am Monica Kraft MD, and I am a professor of Medicine at Duke University and current president of the American Thoracic Society. As both a researcher and a clinician, I have spent most of my professional life dedicated to the diagnosis and management of patients with asthma and I direct the Duke Asthma, Allergy and Airway Center at Duke. It is with this professional and scientific background that I offer to present testimony of the American Thoracic Society on legislation to restore epinephrine inhalers back on the U.S. market place. It is my strongly held view and the view of the American Thoracic Society, that returning epinephrine inhalers to the U.S. market, even for a limited time, would be ill advised.

This view is shared by several other physician organizations including, the American Academy of Allergy Asthma and Immunology, the American College of Asthma Allergy and Immunology, the American Association of Respiratory Care and the National Association for the Medical Direction of Respiratory Care.

Asthma

As background, asthma is common and potentially life threatening medical condition where the airways of lung are inflamed, severely restricting air flow to the lung. For many people with asthma, it can feel like breathing through a straw.

Asthma affects between 5 and 10% of the population, so most everyone knows someone who has asthma. Therefore, over 24.6 million Americans have physician diagnosed asthma, including 7.1 million children. While the majority of asthma patients can and will successfully manage their asthma, every year, people die as a result of asthma attacks.

In the lung, the airways are inflamed, which means they are red and swollen which can cause them to narrow then and restrict airflow. The focus of asthma treatment is with anti-inflammatory medications, such as inhaled corticosteroids. In addition, medications that cause the airways to widen (bronchodilate) are also used. In more severe asthma, , physicians try a combination of other drugs to treat asthma which may include medications to more directly treat allergic symptoms, or in the most severe cases, oral corticosteroids such as prednisone,.

Health care professionals play an important role in educating patients about their asthma, including asthma triggers like tobacco smoke, air pollution, and allergens such as pet dander, cockroaches and dust mites, to find the right combination of medications, along with proper drug administration techniques to help people with asthma live full, active lives.

The take away message is that in the majority of cases, asthma can be successfully treated by working with health care professionals to find the right combination of safe and effective medications.

Epinephrine is NOT one of the medications that is considered safe for the treatment of asthma.

Epinephrine

Epinephrine is non-selective bronchodilator. This means that it has effects not only in the lung to bronchodilate but its non-selective nature means it has effects upon other organs such as the heart. Therefore, epinephrine or Primatene® can cause a significantly increased heart rate. This unwanted side effect can lead to cardiac stress and heart attacks in older patients or patients with heart disease.

For years the medical community has recognized the dangerous side effects of epinephrine for the treatment of asthma and has recommended against its use for asthma. In 1999 the American Medical Association 1) urged that warning labels on over the counter epinephrine

inhalers be strengthened to warn patients about the dangers of epinephrine use, 2) encouraged FDA to consider removing inhaled epinephrine from the market and 3) requested studies to determine whether the availability of inhaled epinephrine is a risk factor in asthma morbidity and mortality. The American Medical Association again reaffirmed this position in 2009.

Several expert panels have produced recommendations on the treatment of patients with asthma. None of the expert guidelines recommend the use of inhaled epinephrine --like Primatene Mist--to treat asthma. The National Asthma Education and Prevention Program (NAEPP), an expert panel convened by the National Institutes of Health, has issued treatment guidelines for management of asthma. NAEPP recommends against the use of epinephrine for treating asthma exacerbations stating:

“Drugs of choice for acute bronchospasm: Inhaled route has faster onset, fewer adverse effects, and is more effective than systemic routes. The less beta2-selective agents (isoproterenol, metaproterenol, isoetharine, and epinephrine) are not recommended due to their potential for excessive cardiac stimulation, especially in high doses.

(emphasis added)(2)

The American Thoracic Society strongly encourages any patient who is using over the counter medications--like Primatene Mist CFC--to treat their asthma to see a healthcare provider who can help the patient develop an asthma management plan and recommend more effective and safer medications to manage the asthma. Asthma action plans are dynamic plans that help guide a patient on how to manage their asthma on good days, bad days and those days in between. I have attached a sample asthma action plan with my testimony.

Pending Legislation

One of the goals of today's hearing is to discuss the pros and cons of enacting legislation to either permanently or temporarily restore inhaled epinephrine for the treatment of asthma to the U.S. market. If the intent of the legislation is to restore a safe and effective asthma drug to the market place, then this legislative effort is mis-informed. Inhaled epinephrine is not a safe drug for the treatment of asthma. The adverse side effects of epinephrine are serious and well documented. No current clinical practice guideline for the diagnosis and treatment of asthma recommends the use of epinephrine. In fact, asthma guidelines specifically recommend against inhaled epinephrine for treating asthma.

If the legislative intent is to provide access to an inexpensive drug for the treatment of asthma, then the legislative effort is laudable, but mis-directed. Inhaled epinephrine's risks outweigh its benefits.

I am also concerned about sending a very confusing message to patients. Physicians, drug makers and retailers have spent a lot of time and effort educating patients about the Primatene Mist transition and treatment alternatives patients have now that Primatene Mist is no longer available. Putting Primatene Mist back on the market – for an indefinite period of time – will send a very confusing message to patients.

Congress should be considering ways to increase patient access to health care professionals who can work with patients to find an effective combination of drugs to control asthma. We should not be abandoning patients with a serious medical condition like asthma to self diagnosis and self medication with less effective drugs that have well known serious side effects.

I hope the committee will keep the view of the American Thoracic Society in mind as it considers legislation on inhale epinephrine for the treatment of asthma. I would be happy to answer any questions you may have.

- 1) AMA House of Delegates policy H-115.972 (CSA Rep.2 A-99, reaffirmed CSPH Rep. 1 A-09)
- 2) National Asthma Education Prevention Program– Expert Report 2 (1997) p. 64 figure 3-2.